Draft Guidance for Industry and FDA Staff

Class II Special Controls Guidance Document: Cutaneous Electrode

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.
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Food and Drug Administration
Center for Devices and Radiological Health

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Division of Ophthalmic, Neurological, and Ear, Nose and Throat Devices
Office of Device Evaluation

Preface

Additional Copies

Additional copies are available from the Internet at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm199247.htm. You may also send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the guidance or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number (1572) to identify the guidance you are requesting.

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1. Introduction

This draft guidance document was developed as a special controls guidance for this class II device and to support the exemption from premarket notification (510(k)) requirements of the Federal Food, Drug, and Cosmetic Act (the act) of the cutaneous electrode (see sections 510(m) and 513(a)(1)(B) of the act; 21 USC 360(m) and 360c(a)(1)(B)). A cutaneous electrode is an electrode that is applied directly to a patient's skin either to record physiological signals (e.g., the electroencephalogram) or to apply electrical stimulation.

This draft guidance is being issued in conjunction with a Federal Register notice announcing a proposal to designate a special controls guidance and to exempt this device type from the premarket notification requirements of the act if the manufacturer follows the recommendations in the special controls guidance document. This guidance is issued for comment purposes only. If a final rule is not issued designating this guidance as a special control, then the guidance will not be issued in final form.

This draft guidance document describes a means by which cutaneous electrodes may comply with the requirement of class II special controls (513(a)(1)(B) of the act). Designation of this guidance document as a special control will mean that manufacturers of cutaneous electrodes will need to address the issues identified in this special controls guidance document. However, if the regulation is finalized designating this guidance as a special control, a manufacturer need only show that its device meets the special controls by following the recommendations of the guidance document or in some other way providing equivalent assurances of safety and effectiveness. Under section 510(m), FDA is also proposing to exempt from the requirement of premarket notification certain devices falling within this classification. If the proposed rule is finalized, manufacturers who follow the specific measures recommended in this guidance will be able to market their device without being subject to the premarket notification requirements of section 510(k) of the act, subject to the limitations on exemption in 21 CFR 882.9.[1] Manufacturers who choose to provide other equivalent assurances of safety and effectiveness will need to submit a 510(k) and receive marketing clearance for their device.

[1] We recommend that manufacturers document how they address the recommendations of this guidance in their design history file. Manufacturers must maintain design controls, including a design history file, in accordance with 21 CFR 820.30.

2. Scope

The scope of this document is limited to the cutaneous electrode, 21 CFR 882.1320 (see below), class II, product code GXY.

> Section 882.1320 Cutaneous electrode—
>
> Identification. A cutaneous electrode is an electrode that is applied directly to a patient's skin either to record physiological signals (e.g., the electroencephalogram) or to apply electrical stimulation.

Electrocardiograph (ECG) electrodes are classified separately under 21 CFR 870.2360 and, therefore, do not fall within the scope of this guidance document.

3. Risks to Health

In the table below, FDA has identified the following risks to health associated with the use of the cutaneous electrode. We recommend the following measures to mitigate the risks identified in this guidance document.

Identified risk	**Recommended mitigation measures**
User discomfort or injury	Sections 5 and 6
Adverse reactions to the skin-contacting electrode materials	Sections 5 and 6
Inaccurate clinical diagnosis based on impaired quality of the recorded physiological signal	Sections 5 and 6

4. Device Description

Under 21 CFR 820.181(a), the device master record must include or reference the following, for each type of device:

- specifications, including appropriate drawings
- composition
- formulation
- component specifications
- software specifications.

Accordingly, we recommend that you maintain a complete description of the device and all accessories in the device master records. This description should include the following:

- identification of the device, by the regulation number and product code described in

Section 2 above

- a written description of the device, including all device accessories
- identification of the relevant dimensions and weight of the device or accessory
- a description of how the device interconnects with other components
- engineering drawings or photographs of the device
- a detailed table listing all of the relevant features and specifications of the device.

5. Performance Characteristics

Under the Design Controls section of the Quality System Regulation (21 CFR 820.30), each device manufacturer must establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met. In meeting the design validation component of these design control requirements, each manufacturer must validate its device design, i.e., establish by objective evidence that device specifications conform to defined user needs and intended uses (21 CFR 820.3(z)(2)). The results of design validation must be documented in the design history file (DHF) (21 CFR 820.30(g)). We recommend that manufacturers evaluate their devices as described below and, where appropriate, document the results in their design history files as a part of the Design Controls requirements (21 CFR 820.30). We recommend that you also maintain the information below in your device master records (21 CFR 820.3(j)) to document your device's specifications and performance characteristics.

A. Electrodes

We recommend that you specify the materials, construction, type, and size of the electrodes. To assure that the device performs as intended, we also recommend that you evaluate and document the electrodes' biocompatibility, electrical performance, adhesive performance, stability, and, if applicable, suitability for reuse.

1. Biocompatibility

The skin-contacting materials, such as the electroconductive gel layer, should be biocompatible for their intended use. To determine the applicable device category and tests, you should consult ANSI/AAMI/ISO 10993-1:2003, *"Biological evaluation of medical devices -- Part 1: Evaluation and testing."* This FDA-recognized standard recommends evaluation and testing of medical devices based upon the duration and type of contact. For cutaneous electrodes with a limited contact duration (e.g., less than 24 hours), we recommend the following tests to establish material safety: dermal irritation, sensitization, and cytotoxicity.

The electrodes should be tested under their intended conditions of use, e.g., duration and method of application. The electrodes should not contain or produce toxic or electrolytic products that could result in an irritating, sensitizing or cytotoxic effect upon the skin or enter beneath the skin by iontophoresis. However, due to the electrolytic composition of

some electroconductive gels that contain high levels of saline, a positive cytotoxicity result may not be a correct indication that the hydrogel is truly cytotoxic. In these circumstances, evaluation using other tests specified in the standard may be appropriate.

2. Electrical Performance

If the electrode is intended to apply electrical stimulation, the electrode design should ensure that the energy from the waveform/pulse generator is efficiently transferred to the patient. For both recording and stimulation applications, we recommend that you perform impedance testing to assure that the electrode has conductive properties appropriate to the device's intended use. For recording applications (e.g., EEG or EMG), we recommend that you follow sections 4.2.2, 5.2.2, and A.4.2.2 of ANSI/AAMI EC12:2000, *"Disposable ECG Electrodes,"* to assure appropriate electrical performance regarding AC impedance, DC offset voltage, combined offset instability and internal noise, and DC bias current tolerance.

The construction of cutaneous electrodes should ensure that the electrodes distribute electrical current reasonably uniformly across the electrode-skin interface, and avoid "hot spots" that may result in user discomfort or skin burns.

3. Adhesive Performance

The electrode design should ensure that the electrodes will adhere to the patient's skin for a duration of use compatible with the intended use of the device. We recommend that you perform testing to assure that the electrode's adhesive performance meets the specified design requirements and user needs.

4. Stability

Cutaneous electrode materials should be stable and resist physical and chemical breakdown as a result of conducting electrical current and extended periods of storage over a range of environmental conditions. We recommend that you perform testing to establish, for labeling purposes, the device's shelf life and storage conditions.

5. Reuse

If the electrodes are not limited to single-patient use, we recommend that the labeling include instructions for handling, transport, cleaning, and biological decontamination to ensure the safety and protection of patients and health care or other personnel who perform these tasks. For reusable electrodes, you should follow the FDA-recognized standard, ANSI/AAMI ST35:2003, *"Safe handling and biological decontamination of reusable medical devices in health care facilities and in nonclinical settings."* You should evaluate the potential for skin reactions and disease transmission, as well as demonstrate that the cleaning and biological decontamination of the electrodes provides sufficient protection and does not impact their functional performance. In general, we believe pre-gelled electrodes cannot be cleaned and decontaminated in a manner that assures prevention of cross-contamination skin reactions or disease transmission; therefore, we recommend that these electrodes be limited to single-patient use.

B. Electrode Conductive Medium (Gel)

The conductive media or gels used with cutaneous electrodes are regulated as class II devices under 21 CFR 882.1275. FDA is also proposing to designate a special control and exempt these electroconductive media from premarket notification requirements under section 510(k) of the act in the proposed rule issued with this draft guidance. See also the draft guidance document entitled **Class II Special Controls Guidance Document: Electroconductive Media**[2], when finalized, for specific recommendations on the types of information to document for this accessory.

C. Electrode Lead Wires and Patient Cables

The electrode lead wires and patient cables intended for use with a medical device are subject to the mandatory performance standard set forth in 21 CFR Part 898. The electrode lead wires and patient cables must be in compliance with the test requirements and test methods of subclause 56.3(c) of IEC 601-1 (1998), *"Medical Electrical Equipment - Part 1: General Requirements for Safety,"* Amendment No. 1 (1991), and Amendment No. 2 (1995), see 21 CFR 898.12(a). If the cutaneous electrode includes a lead wire, your documentation should contain information sufficient to demonstrate conformance to this mandatory performance standard.

6. Labeling

The following suggestions are intended to help you prepare labeling that satisfies the requirements of 21 CFR Part 801.[3]

Package Insert

We recommend that you provide a package insert with the device.[4] The insert should include the following:

- model number and name, quantity, dimensions, and type of electrodes
- identification of size and type of connection to lead wire
- date of manufacture, shelf life, and lot number
- storage instructions
- instructions for skin preparation
- instructions for electrode preparation and application

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[2] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm199256.htm.

[3] Labeling must comply with the requirements of 21 CFR Part 801 before a medical device is introduced into interstate commerce. Labeling recommendations in this guidance are consistent with the requirements of 21 CFR Part 801.

[4] Devices not restricted to prescription use must contain adequate directions for use in accordance with 21 CFR 801.5 and section 502(f) of the act.

- instructions regarding maximum duration of use
- handling and cleaning instructions (refer also to the **Reuse** paragraph above).

Your device labeling must include adequate directions for use in accordance with 21 CFR 801.5. Under this rule, your labeling (e.g., package insert) must describe the intended use of the device, and include a listing of contraindications, warnings, precautions, and adverse reactions, relevant to your device (21 CFR 801.5(a)). This information must be prominently placed on the labeling (21 CFR 801.15). The labeling recommendations below are not intended to capture all possible limitations or instructions for all cutaneous electrodes. Therefore, when developing adequate directions for use, it may be necessary for you to include additional limitations (e.g., contraindications, warnings, precautions, adverse reactions), and other instructions that are appropriate for your device, depending on its specific design, features, and performance characteristics.

Intended Use

The cutaneous electrodes covered by this guidance document are those intended for recording physiological signals (e.g., the electroencephalogram) or applying electrical stimulation.

Contraindication

We recommend that the package insert include the following statement:

- Do not use cutaneous electrodes for stimulation (stimulation electrodes) if you have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device. Such use could cause electric shock, burns, electrical interference, or death.

Warnings

We recommend that the package insert advise users of the following:

- Do not place stimulation electrodes over your neck because this could cause severe muscle spasms resulting in closure of your airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure;
- Do not place stimulation electrodes across your chest because the introduction of electrical current into the chest may cause rhythm disturbances to your heart, which could be lethal;
- Do not place stimulation electrodes over open wounds or rashes, or over swollen, red, infected, or inflamed areas or skin eruptions (e.g., phlebitis, thrombophlebitis, varicose veins); and
- Do not place stimulation electrodes over, or in proximity to, cancerous lesions.

We also recommend that the package insert advise the following:

- Electrodes should be applied only to normal, intact, clean, healthy skin;
- The size, shape, and type of electrodes may affect the safety and effectiveness of electrical stimulation and recording;

- The electrical performance characteristics of electrodes may affect the safety and effectiveness of electrical stimulation and recording;
- Using stimulation electrodes that are too small or incorrectly applied could result in discomfort or skin burns; and
- You should contact the manufacturer of the electrical stimulator or recording device if you do not know if the electrode can be used with the stimulation or recording device.

For pre-gelled electrodes and other electrodes that cannot be fully cleaned and decontaminated between uses, we recommend that the package insert advise users not to share electrodes with other persons because of the risks of adverse skin reactions and disease transmission.

Precautions

We recommend that the package insert advise users of the following:

- The long-term effects of cutaneous electrodes for electrical stimulation and/or recording are unknown; and
- Since the effects of stimulation of the brain are unknown, stimulation electrodes should not be placed on opposite sides of your head.

The package insert also should advise users of the following:

- Keep electrodes out of the reach of children;
- Use caution if electrodes are applied over areas of skin that lack normal sensation; and
- Replace self-adhesive electrodes if they no longer stick firmly to your skin.

Adverse Reactions

We recommend that the package insert include known adverse reactions as in the examples below:

- You may experience skin irritation and burns beneath the stimulation electrodes applied to your skin; and
- You may experience headache and other painful sensations during or following the application of electrical stimulation near your eyes and to your head and face.

7. Limitations of Exemption from Premarket Notification

FDA's decision to exempt a class II device from the premarket notification requirement of the act is only to the extent that the device has existing and reasonably foreseeable characteristics of devices within that generic type that currently are, or have been, in commercial distribution. Section 21 CFR 882.9 specifies the limitations on exemption. If any of these limitations apply, your device is not exempt, and you must submit a premarket notification.